

### **REMARKS**

After entry of this amendment, claims 11-13, 16, 20-22, 24, 33, 34, 38-40, and 47-55 are pending. Claims 1-10, 14, 15, 17-19, 23, 25-32, 35-37, and 41-46 are cancelled without prejudice or disclaimer. Claims 11, 24 and 38-40 have been amended without prejudice or disclaimer and find support *inter alia* in the original claims. Amendments to claims 11 and 24 find further support in the specification, for example, at pages 6-8 paragraphs [018]-[026] and in Examples 11-16. New claim 49 finds support in original claims 10, 16, and 24 and in the specification, for example, at pages 30-31 paragraphs [075]-[078]. New claims 48, 50-52 and 55 find support in original claims 38-41 and in the specification, for example, at pages 5-7 paragraphs [012] and [018]. New claims 53-54 find support in original claims 6 and 24 and in the specification, for example, at page 15 paragraph [038], at pages 20-21 paragraph [049]. No new matter has been added.

### **Rejections under 35 U.S.C. § 102**

Claims 10-13, 16, 20-22, 24, 33, 34, 37, 38, 40 and 47 are rejected under 35 U.S.C. § 102(b) as anticipated by Dormann *et al.* (hereinafter "Dormann"). Claims 10 and 37 have been cancelled without prejudice or disclaimer and as such the rejection as to these claims is rendered moot.

Applicants respectfully disagree and traverse the rejection. Nonetheless, in order to expedite prosecution, the claims have been amended without prejudice or disclaimer. Claim 11 relates to a method of producing a transgenic plant having an increased level of fatty acids which also comprises analyzing the production of fatty acids in seeds of the transgenic plant, and selecting a transgenic plant having an increased level of fatty acids as compared to an untransformed wild type variety of the plant. The method of claim 24 relates to a method of increasing the level of fatty acids in seed of a plant which comprises selecting a transgenic plant having an increased level of fatty acids as compared to an untransformed wild type variety of the plant.

The Examiner alleges that the increase in level of a seed storage compound would be inherent in a plant transformed with the same gene and in a method comprising the same steps. Applicants strongly disagree. Nonetheless, in light of the present amendments to expedite prosecution, the rejection is believed to be rendered moot.

Moreover, the Federal Circuit held that "unless a reference discloses within the four corners of the document not only all the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102." *Net MoneyIN Inc. v. VeriSign Inc.*, 545 F.3d 1359 (Fed. Cir. 2008).

In addition to the reasons already of record, Dormann does not disclose a method with a step of analyzing the production of fatty acids in seeds as in present claim 11 or a step of selecting a transgenic plant having an increased level of fatty acids as compared to an untransformed wild type variety of the plant (claims 11 and 24). Because Dormann does not teach every limitation of the claims, Dormann does not anticipate the claims.

Reconsideration and withdrawal of this rejection is respectfully requested.

**Rejections under 35 U.S.C. § 103**

Claims 10-13, 16, 20-22, 24, 33, 34, 37-40, and 47 are rejected under 35 U.S.C. § 103(a) as being obvious over Dormann in view of Goodman (U.S. Patent No. 4,956,282). Applicants respectfully traverse. Claims 10 and 37 have been cancelled without prejudice or disclaimer and as such the rejection as to these claims is rendered moot.

Applicants respectfully disagree with the Examiner's characterization of the claims and the references cited for the reasons already of record and for the following additional reasons. Nonetheless, in order to expedite prosecution, claims have been cancelled or amended without prejudice or disclaimer. Claim 11 relates to a method of producing a transgenic plant having an increased level of fatty acids which comprises analyzing the production of fatty acids in seeds of the transgenic plant, and selecting a transgenic plant having an increased level of fatty acids as

compared to an untransformed wild type variety of the plant. The method of claim 24 relates to increasing the level of fatty acids in the seed of a plant which comprises selecting a transgenic plant having an increased level of fatty acids as compared to an untransformed wild type variety of the plant.

The Examiner bears the initial burden of establishing *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

Dormann teaches a method for complementing the *dgd1* Arabidopsis mutant and producing a transgenic mutant plant with wild type lipid composition. The method disclosed in Dormann resulted in transgenic mutant plants with lipid compositions that were the same as the wild type. “Two transgenic plants were recovered and both were phenotypically wild type with regard to growth habit and lipid composition” and “Cosmid C49B and the *DGDI* cDNA lead to wild-type lipid composition in all tested transgenic plants homozygous for *dgd1*.” (Dormann, page 2183, third column, first paragraph). Dormann thus teaches restoring the wild type phenotype in a mutant transformed with the Cosmid C49B and the *DGDI* cDNA. Restoring expression in leaves of a deficient mutant to the level of the wild type does not teach or suggest the effect that expression of *DGDI* alone has on seed fatty acid levels in a transgenic plant when compared to an untransformed wild type plant. Restoring expression in leaves of a deficient mutant to the level of the wild type does not teach or suggest increasing fatty acid levels in seed when compared to the wild type.

Additionally, Dormann does not teach or suggest a method with a step of analyzing the production of fatty acids in seeds or a step of selecting a transgenic plant having an increased level of fatty acids as compared to an untransformed wild type variety of the plant.

The Examiner acknowledged that Dormann does not teach transformation of monocots and previously acknowledged that Dormann does not teach “modified or increased as compared

to the wild type variety of the plant.” (Office Action dated July 23, 2008, page 14). The Examiner now relies on Goodman for a method for transformation of monocot plant species.

However, Goodman does not remedy the deficiencies of Dormann. Goodman teaches the expression of *mammalian proteins* in plant cells. As with Dormann, Goodman does not teach a method of producing a transgenic plant having an increased level of fatty acids in seed or a method for increasing the level of fatty acids in seed. Because none of the references cited by the Examiner teach or suggest all the limitations of the claimed invention, a *prima facie* case of obviousness has not been established for this reason alone.

Moreover, a reasonable expectation of success must be established for a proposed combination of references to render claims *prima facie* obvious. See MPEP § 2143.02 (citing *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)). In addition, the record must provide evidence that those of skill in the art would have had a reasonable expectation of success in doing so. The reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. See *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

Dormann teaches that the relative amount of digalactosyldiacylglycerol (DGD) is reduced as a fraction of total polar lipids in leaves of the *dgd* mutant grown in tissue culture. (Dormann, page 2182, Table 1). Dormann is silent on the effect of the *dgd* mutation or DGD1 on overall fatty acid levels or fatty acid levels in seed. In addition, Dormann discloses that there are two DGD genes in *Arabidopsis* and that “[i]n the absence of DGD1, monogalactosyl lipid cannot be efficiently synthesized via the ER pathway but the plastid pathway can compensate for this deficiency.” (Dormann, p. 2182, end of middle column to top of right column). Dormann thus discloses that there is strong regulation between the two pathways involved in galactosyl lipid biosynthesis.

The Examiner maintains that Dormann allegedly teaches an increase in some seed storage compounds (Office Action dated April 7, 2009, page 4), but without any further explanations. “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there

must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) quoting *In re Kahn*, 441 F.3d 977, 988, (Fed. Cir. 2006). Dormann does not teach or suggest that expression of one DGD alone would result in increased content of fatty acids or increased content of fatty acids in seeds.

Rather in Table 1, Dormann shows that the relative amount of monogalactosyldiacylglycerol (MGD) slightly increases in the *gdg* mutant. Dormann teaches that this is consistent with the precursor function of MGD in digalactosyl lipid biosynthesis (Dormann, page 2182, first column, first full paragraph). Dormann teaches that the transient pool of monogalactosyl lipid produced at the outer envelope from ER-derived diacylglycerol is immediately converted to *DGD1* (Dormann, page 2182, middle column, first full paragraph). Thus, the downstream disruption of the pathway in the *gdg1* mutant would result in the accumulation of the precursors. Moreover, Dormann teaches that the biosynthesis of galactolipids at the outer envelope membrane (e.g. ER pathway) cannot compensate for biosynthesis by *DGD1* which explains the small amount of digalactosyl lipid and altered molecular species composition of monogalactosyl lipid in *gdg1* mutant (Dormann, page 2182, right column). Thus the relative increase of MGD in the mutant can be attributed to the *gdg1* disruption where the MGD precursor is hampered from further processing in the biosynthesis pathway. Contrary to the Examiner’s assertion, Dormann does not teach or suggest an increase in fatty acids or an increase in fatty acids in seed by expression of one DGD alone in a transgenic wild type plant, but rather a disruption in the pathway preventing further biosynthesis of the precursor.

Moreover, Dormann teaches that expression of *DGD1* in the *gdg* mutant leads to the wild type lipid composition, simply restoring the deficient mutant to its wild type level. Dormann does not teach or suggest the effect of *DGD1* expression on fatty acid levels. Dormann also does not teach or suggest the effect of the *gdg* mutation or *DGD1* expression on seed fatty acid levels or that *DGD1* expression in a wild type plant results in a plant with increased fatty levels or fatty acid levels in seed. In contrast, the present application demonstrates in a working example that

expression of an LMP nucleic acid in a wild type plant increases fatty acid levels in seed compared to an untransformed wild type plant (see Specification, for example, Example 15 and at page 64 paragraph [0163] and page 68 paragraph [0175]). Moreover, given that Dormann also discloses that there are two DGD genes in *Arabidopsis* and strong regulation between the two pathways for galactosyl lipid biosynthesis, there would be no expectation of success that expression of one DGD alone in a wild type plant would result in increased content of fatty acids or fatty acids in seed. A *prima facie* case of obviousness has not been established for this additional reason.

Furthermore, the Examiner now relies on Goodman for a method for transformation in monocots. However, the substitution of a *plant DGD gene* in a *mammalian gene construct* would be needed for the method of Goodman to be applicable and combinable with Dormann. The Patent Office has still not provided any reasoning for the substitution a *mammalian protein* such as interferon with a *lipid metabolism plant protein* when using the method of Goodman for transformation of monocot plant species (see also Amendment and Reply Under 37 CFR § 1.111 dated December 16, 2008). The Examiner argues that the obviousness rejection has been restated. However, *KSR* still requires some reason that would have prompted a person of skill in the art to combine Dormann and Goodman and as such some reason for the substitution a *mammalian protein* such as interferon with a *lipid metabolism plant protein*. *KSR International Co. v. Teleflex Inc.*, 1741 82 USPQ2d 1385, 1396 (2007) (emphasis added) (holding that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. . . it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does.*”) (emphasis added). The Examiner has thus still not provided the requisite explanation, rationale, or suggestion in the references cited how the combination would arrive at the same result or how it arrives at the claimed invention or for why it would be obvious to substitute these genes. Accordingly, a *prima facie* case of obviousness has not been established for this additional reason and as such Dormann and Goodman are not combinable.

Moreover, a prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *See* MPEP § 2141.03 (VI) (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)). It is improper to combine references where the references teach away from their combination. *See* MPEP § 2145 (X)(D)(2) (citing *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).

Given the teaching of Dormann that there are two DGD genes in *Arabidopsis* and that there is strong regulation between the two pathways for galactosyl lipid biosynthesis, a person skilled in the art would rather be led away from using one DGD alone. In addition, because Dormann and Goodman disclose totally different genes from different sources and involved in totally different pathways, Dormann and Goodman are not combinable for this additional reason.

Even assuming *arguendo* that they were combinable, there is no teaching or suggestion for the desirability to express one DGD alone in a wild type plant for increasing the level of fatty acids in seed compared with an untransformed wild type plant or that mammalian genes for production of physiologically active proteins like interferon are substitutable for plant DGD genes for increasing the level of fatty acids in seed in a monocot plant. *In re Mills*, 916 F.2d 680, 682, 16 USPQ2d 1430 (Fed. Cir. 1990) (the Examiner cannot selectively pick and choose from the disclosed parameters without proper motivation as to a particular selection. The mere fact that a reference may be modified to reflect features of the claimed invention does not make the modification, and hence the claimed invention, obvious unless the prior art suggested the desirability of such modification); *In re Fritch*, 23 USPQ2d 1780 (Fed. Cir. 1992).

In summary, because Dormann and Goodman, alone or in combination, do not disclose or teach all the limitations of the present claims, because there is no expectation of success, and because Dormann and Goodman are not combinable, Dormann and Goodman, alone or in combination, do not render obvious the subject matter of the independent claims or the claims dependent therefrom. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

Reconsideration and withdrawal of the rejection is respectfully requested.

**CONCLUSION**

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Accompanying this response is a petition for a two-month extension of time to and including September 7, 2009 with the required fee authorization. No further fee is believed due. However, if an additional fee is due, the Director is authorized to charge our Deposit Account No. 03-2775, under Order No. 12810-00379-US from which the undersigned is authorized to draw.

Respectfully submitted,

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